

Subpart D—Equipment and Utensils

§ 111.25 What are the requirements under this subpart D for written procedures?

You must establish and follow written procedures for fulfilling the requirements of this subpart D, including written procedures for:

- (a) Calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement;
- (b) Calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and
- (c) Maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements.

§ 111.27 What requirements apply to the equipment and utensils that you use?

(a) You must use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained.

(1) Equipment and utensils include the following:

- (i) Equipment used to hold or convey;
- (ii) Equipment used to measure;
- (iii) Equipment using compressed air or gas;
- (iv) Equipment used to carry out processes in closed pipes and vessels; and
- (v) Equipment used in automated, mechanical, or electronic systems.

(2) You must use equipment and utensils of appropriate design and construction so that use will not result in the contamination of components or dietary supplements with:

- (i) Lubricants;
- (ii) Fuel;
- (iii) Coolants;
- (iv) Metal or glass fragments;
- (v) Filth or any other extraneous material;
- (vi) Contaminated water; or
- (vii) Any other contaminants.

(3) All equipment and utensils you use must be:

(i) Installed and maintained to facilitate cleaning the equipment, utensils, and all adjacent spaces;

(ii) Corrosion-resistant if the equipment or utensils contact components or dietary supplements;

(iii) Made of nontoxic materials;

(iv) Designed and constructed to withstand the environment in which they are used, the action of components or dietary supplements, and, if applicable, cleaning compounds and sanitizing agents; and

(v) Maintained to protect components and dietary supplements from being contaminated by any source.

(4) Equipment and utensils you use must have seams that are smoothly bonded or maintained to minimize accumulation of dirt, filth, organic material, particles of components or dietary supplements, or any other extraneous materials or contaminants.

(5) Each freezer, refrigerator, and other cold storage compartment you use to hold components or dietary supplements:

(i) Must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device that indicates and records, or allows for recording by hand, the temperature accurately within the compartment; and

(ii) Must have an automated device for regulating temperature or an automated alarm system to indicate a significant temperature change in a manual operation.

(6) Instruments or controls used in the manufacturing, packaging, labeling, or holding of a dietary supplement, and instruments or controls that you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), water activity, or other conditions, to control or prevent the growth of microorganisms or other contamination must be:

- (i) Accurate and precise;
- (ii) Adequately maintained; and
- (iii) Adequate in number for their designated uses.

(7) Compressed air or other gases you introduce mechanically into or onto a component, dietary supplement, or contact surface or that you use to clean any contact surface must be